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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,061

05/09/2005

Mitsuhiko Hori

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02/14/2008

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,061	Applicant(s) HORI ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a patch comprising 2-amino-1-(2',5'-dimethoxyphenyl)ethanol.

Group II, claims 10-12, drawn to a method of making a patch comprising 2-amino-1-(2',5'-dimethoxyphenyl)ethanol.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a patch comprising 2-amino-1-(2',5'-dimethoxyphenyl)ethanol, comprising a non-crosslinked adhesive layer laminated to a substrate surface and a crosslinked adhesive layer laminated (adhered or bonded) to the non-crosslinked adhesive layer. Otsuka et al. (JP59172418 – English translation – citation found on 892) teach the same technical feature where a patch is taught that has drug, and both a non-crosslinked adhesive and cross-linked adhesive laminated (adhered or bonded) to the surface of a substrate (see page 2 paragraph 1). The drug is taught to be included in the non-crosslinked layer (see page 3 paragraph 3). Otsuka et al. do not specifically teach 2-amino-1-

Art Unit: 1615

(2',5'-dimethoxyphenyl)ethanol, also known as desglymidodrine, as the included drug. Sundgreen et al. (US PGPub No. 2002/0147232) does teach a composition comprising desglymidodrine, and specifically in a patch configuration (see paragraph 2 and 180). It therefore would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Otsuka et al. and Sundgreen et al. to produce a composition with the same technical feature as the instant inventions. Thus since, taught common technical feature is known in the art, this technical feature cannot be deemed as special.

Should Group I be elected, the following election of species is also required.

Election

Claims 1-9 are generic to the following disclosed patentably distinct species: patches comprising 2-amino-1-(2',5'-dimethoxyphenyl)ethanol. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record and require separate prior art queries. Should Group I be elected, the applicant must also make a selection for each of the following:

- The presence or absence of a long chain fatty acid ester and/or long chain aliphatic alcohol in layer A and/or B (indicate whether either are present and if so in which layer or layers)
- Whether layers A and B have the same composition

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and species.

Art Unit: 1615

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions (or species) are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions (or species) to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions (or species) unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention (or species).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615

Caralynne Helm
Examiner
Art Unit 1615

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